

REMARKS

Claims 1-21 are pending, claims 5, 8-12 and 15-20 are withdrawn. By this Amendment, Applicants amended claims 1 and 6. Claims 7, 13 and 14 have been amended to correct minor errors and claims 4 and 21 have been cancelled. No new matter has been added

Rejection of Claims 1, 3, 4, 6, 13, 14 and 21 under -35 U.S.C. §102(b) as allegedly anticipated under 35 U.S.C. and obvious under 35 U.S.C. §103(a) over Okada et al. (US 6,455,053) has been maintained. Claim 6 remains rejected under 35 U.S.C. §112, first paragraph, for alleged lack of written description.

Applicants respectfully request reconsideration and allowance of all pending claims in view of the amendment to the claims and the remarks set forth below.

Anticipation Rejection Over Okada

The Examiner has maintained the rejection of claims that recite a drop pill comprising a pharmaceutical active and a matrix adjuvant over Okada et al. The applicant believes that the claimed drop pills are remarkably different from the rapidly dissolving solid preparation disclosed by Okada et al. in preparing method as well as their structure and properties.

The rapidly dissolving solid preparation disclosed by Okada et al. is characterized by the procedure in which, a drug as well as a saccharide are dissolved and dispersed in an aqueous solution, an organic solvent, or the like, resulting in a suspension composition, and the resultant is dried to obtain the rapidly dissolving solid preparation. (Please refer to the records in lines 26-33 in Column 2).

Thus, the objective of Okada et al. is to provide a rapidly dissolving solid preparation which disintegrates and dissolves rapidly in the oral cavity and has a practical hardness. The solid preparations prepared by the methods disclosed by Okada et al. have much shorter disintegration time. As opposed to the “drop pill” as claimed in the present invention, the disintegration time of the preparations of Okada’s invention is less than 79.8 seconds, as shown in tables 1-5 and the disintegration time of the claimed drop pills in the present invention is 2.68 minutes (See Example 35) to about 5.67 minutes (Example 47). In addition, the dissolution time in the oral cavity of the rapidly dissolving preparations of Okada’s invention is shorter (about 1 minute or less, see tables

1-5).

The differences in structure and properties between the claimed drop pills and the rapidly dissolving preparation disclosed by Okada et al. are summarized in Table 1 below.

Table 1

structure and properties	Claimed drop pills	Rapidly dissolving solid preparation disclosed by Okada et al.
structure	dense	loose
Micro-pores in structure	none	many
surface	smooth	rough
homogeneity	high	low
density	high	low
hardness	high	low
friability	low	high
hygroscopicity	low	high

The applicant considers that the different preparing methods result in different structure and properties of the products as claimed in independent claim 1. Claims 3, 6 and 13-14 depend from claim 1. Claims 4 and 21 have been deleted. Withdrawal of the anticipation rejection of claims 1, 3, 6, 13 and 14 over Okada et al. is respectfully requested.

Obviousness Rejection Over Okada

The Examiner maintained the rejection of claims 1-4, 6, 7, 13, 14 and 21 as allegedly obvious over Okada et al.

Applicants respectfully disagree and reference the previous section herein above.

To establish a prima facie case of obviousness, the Examiner must show that the prior art discloses, teaches or suggest each limitation of the claims at issue, MPEP §2143.03, or At least provides an “apparent reason” to modify the prior art in the direction of the claimed invention. The Examiner must further show that one skilled in the art would have a reasonable expectation of success to modify the prior art to arrive at the claimed invention.

The objective of Okada et al. is “to provide a rapidly solid preparation which disintegrates and dissolves rapidly in the oral cavity and the like, and has a practical hardness, whereby solving

foregoing problems and a manufacturing method thereof.”

The present invention provides “a natural, safe and non-toxic material derived from plants used as matrix adjuvant or the main components of the matrix adjuvant for drop pills, to promote the development of the drop pills formulation” (See page 3, lines 10-13 of the Specification).

Furthermore, the drop pills according to the present application surprisingly advantages in some aspects over the rapidly dissolving preparation disclosed by Okada et al. The above-mentioned statement show that the claimed drop pills are denser and harder than the rapidly dissolving preparation disclosed by Okada et al., thus is more resistant to pressure. Therefore the claimed drop pills are easier to be packaged and transported. In addition, the claimed drop pills are more resistant to moisture due to its denser structure. So it is more convenient to be stored.

As mentioned above, the drop pill in claim 1 is totally different from the preparation disclosed by Okada et al. Claims 2, 3, 6, 7, 13 and 14 depend from claim 1. Claims 4 and 21 have been deleted. Withdrawal of the obviousness rejection of claims 1-3, 6, 13 and 14 over Okada is respectfully requested.

Written Description Rejection

Amendment of claim 6 makes this rejection moot. Withdrawal of this rejection is respectfully requested.

The Applicants therefore respectfully request reconsideration and allowance in view of the above remarks and amendments. The Examiner is authorized to deduct additional fees believed due from our Deposit Account No. 50-4711.

Respectfully submitted,

KAPLAN GILMAN & PERGAMENT LLP
1480 Route 9 North, Suite 204
Woodbridge, New Jersey 07095
Telephone (732) 636-4500

Dated: April 30, 2009

/Edward D. Pergament/
Edward D. Pergament
(Reg. No. 43,346)